June 30, 2020

Baxter Healthcare Corporation
Phillip Romei
Specialist, Global Regulatory Affairs
32650 N. Wilson Road
Round Lake, Illinois 60073

Re: K201464
Trade/Device Name: Altapore MIS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 19, 2020
Received: June 4, 2020

Dear Mr. Romei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
TBD

Device Name
Altapore MIS

Indications for Use *(Describe)*
ALTAPORE MIS is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis).
ALTAPORE MIS can be used by itself, with autograft as a bone graft extender or with autogenous bone marrow aspirate. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ALTAPORE MIS resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5. 510(k) Summary

June 30, 2020

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Filler, bone void, calcium compound
Trade Name: ALTAPORE MIS
Classification Panel: 87 Orthopedic
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV

Table 1. Model Numbers for Altapore MIS

Model Number	Name
1508032	Altapore MIS System Applicator + Cartridge, 7.5ml
1508047	Altapore MIS System Cartridge, 7.5ml

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Altapore Bone Graft Substitute (Predicate Device)	Baxter Healthcare Corporation	K192363	January 9, 2020
Actifuse™ MIS System Bone Graft Substitute, (Predicate Device)	ApaTech Limited[1]	K082575	November 25, 2008

[1] ApaTech Limited was acquired by Baxter Healthcare Corporation in 2010

The proposed device is substantially equivalent to the predicate devices, Altapore and Actifuse MIS System. Actifuse MIS System is owned and manufactured by Baxter, and has identical packaging, chemical composition, and sterilization as the proposed device. The proposed and predicate Altapore devices have identical chemical composition, physical structure, sterilization, and manufacturing process.

DESCRIPTION OF THE DEVICE:

Altapore MIS System is a is a bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler. The interconnected and open porous structure of the silicate-substituted calcium phosphate phase of Altapore is similar to human cancellous bone and is intended to support bone growth with macro and micro- porosity. Altapore is composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).

Altapore MIS System is supplied in a sterile 7.5ml cartridge and contains Altapore microgranules, sized 1-2 mm, 80-85% total porosity, suspended in an absorbable aqueous gel carrier. Altapore does not set in-situ following implantation.

Altapore MIS System (hereafter referred to as “Altapore MIS) is designed for use as a standalone bone graft substitute or as an autograft extender. While not necessary, the product can be mixed with Bone Marrow Aspirate (BMA) or autologous bone at the discretion of the surgeon.

Altapore MIS is bioactive based on *in vitro* studies that show it forms a surface apatite layer when submerged in simulated body fluid that contains the same ion concentrations as human blood plasma. This apatite layer provides scaffolding onto which the patient's new bone will grow, allowing complete repair of the defect.

Altapore MIS is osteoconductive based on in vivo animal studies that show it achieves bone healing in a critical defect model as confirmed with radiographic, histolopathological, histomorphometric, and mechanical analyses. Altapore MIS undergoes cell-mediated remodeling and is replaced by natural bone.

INDICATIONS FOR USE:

Altapore MIS is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis).

Altapore MIS can be used by itself, with autograft as a bone graft extender or with autogenous bone marrow aspirate. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Altapore MIS resorbs and is replaced with bone during the healing process.

PURPOSE OF SUBMISSION:

The basis for this premarket notification is the addition of the Altapore MIS System configurations to the Altapore product line. The additional configurations consist of a 7.5ml cartridge and delivery applicator and a separate 7.5ml refill cartridge. The proposed new cartridge and applicator materials are currently used in Baxter's Altapore and Actifuse™ MIS System product lines and have been previously cleared under 510(k) premarket notifications K192363 (cleared date 9th Jan, 2020) and K082575 (cleared date 25th Nov, 2008) respectively. The hydroxyapatite granules used in the proposed Altapore MIS System configurations and the predicate devices Actifuse MIS and Altapore are chemically identical. These modifications do not impact the intended use or the fundamental technology of the devices.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed Altapore MIS device has equivalent technological characteristics relative to Baxter's currently cleared Altapore product line, cleared under 510(k) premarket notification K192363 (cleared January 9th, 2020).

DISCUSSION OF NON-CLINICAL DATA:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the proposed devices are appropriately designed for their intended use. All testing was performed on the configuration of the devices presented in this premarket notification.

Performance Data

The performance of the Altapore MIS System device configurations was assessed by analyzing the Altapore MIS System final product for chemical changes relative to the Altapore predicate product's specification. All testing confirmed that the new configurations had no impact to the chemistry or structure of the Altapore MIS System product.

Biocompatibility

All materials found in these devices that are the subject of this submission have been previously cleared under Baxter's 510(k) premarket notifications K192363 (clearance date January 9th, 2020), and K082575 (clearance date November 25th, 2008).

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for permanent duration, implant device, tissue/bone contact, and FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", as recommended in the "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA".

ALTAPORE is non-pyrogenic based on material-mediated pyrogenicity testing conducted per ISO 10993-11 and bacterial endotoxin testing performed per USP<85>.

Sterility

The Altapore MIS System product line is sterilized with radiation. The minimum sterilizing dose (MSD) required to provide a 10^{-6} Sterility Assurance Level (SAL) for this (sub) category was established and validated at the manufacturing facility as described in ANSI/AAMI/ISO 11137-2, "Sterilization of health care products- Radiation-Part 2: Establishing the Sterilization Dose."

These products are labeled "Sterile". Package Verification testing is based on Visual Inspection, Seal Strength, and Bubble Leak testing.

Shelf Life

Testing performed on representative samples supports a shelf-life claim of two (2) years for Altapore MIS.

CONCLUSION:

Altapore MIS System is as safe and effective as the predicate Altapore Bone Graft Substitute. Both devices share indications for use, technological characteristics, and

principles of operation. The only differences between the two devices are the changes to the dimensions and materials of the containers housing the devices. The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device.